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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,937	05/28/2002	Brent C. Gerberding	S63.2-10447	2387
490	7590	01/24/2006		
VIDAS, ARRETT & STEINKRAUS, P.A. 6109 BLUE CIRCLE DRIVE SUITE 2000 MINNETONKA, MN 55343-9185			EXAMINER HOUSTON, ELIZABETH	
			ART UNIT 3731	PAPER NUMBER

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/063,937	GERBERDING, BRENT C.	
	Examiner	Art Unit	
	Elizabeth Houston	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 09 November 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-10,13-18,22-28,34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1,2,4-10,13-18,22-28,34 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Amended claim 1 states "each curved region having a first end and a second end with a middle portion there between, the first end and the second end being more proximal to the special strut than is the middle portion." Examiner directs attention to Figure 1e, a portion of a compressed stent. This figure shows that all portions of the "complementary" struts are equally spaced from the edge of the radiopaque marker. The first end and the second end are the same distance from an edge of the marker as the middle portion is. Figures 1a-1c depict an expanded stent and also do not show this feature. Since the "complementary struts" are angled away from the marker, one end is closer to the marker than the middle portion but the other end is spaced farther than part of the middle portion.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

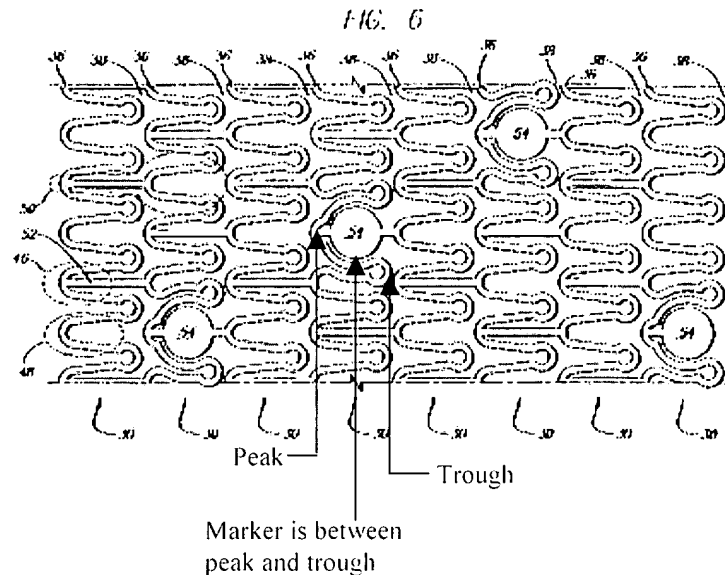
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-2, 4-5, 7-10, 15, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of Erbel.

5. Cox discloses the stent in claim 16 and 17 as stated above. As to claim 1, in one embodiment, Cox clearly teaches a stent having a longitudinal axis, comprising a plurality of serpentine bands formed of interconnected struts (Figs. 6) including: special struts (54), which extend between peaks and troughs (see below) having a first side with a first region of first curvature relative to the longitudinal axis and a second side with a second region of second curvature relative to the longitudinal axis, the first region opposite the second region and having a radiopaque marker (Col. 3, line 14) between the two regions. Each special strut has a plurality of interconnected struts adjacent the first side and a plurality of interconnected struts adjacent the second side, each having curved regions that curve about marker. Each curved region has a first end and a second end being more proximal to the special strut than is the middle portion. The special struts are located between the ends of the stent. Some of the special struts (54b or 54c) are located anywhere between the middle of the stent and halfway from the

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middle to the end of the stent. In other embodiments disclosed by Cox (Figs. 11-15), there is a plurality of radiopaque markers and special struts at the end of the stent.



6.

7. Cox does not disclose a stent with a cover.

8. Erbel discloses an endovascular prosthesis (Fig. 3) or stent (20) comprising at least one cover (25) disposed about at least one section of interconnected serpentine segments, marked at the distal end and proximal end by a plurality of radiopaque markers (35). Erbel teaches that the "use of such radiopaque markers facilitates correct placement" of the stent (Para 90). The nonporous section (25) or cover is disposed about the circumference of the stent, but does not extend about an entire circumference of the stent and does not cover the entirety of the stent as seen in Fig. 3. The cover extends about the medical device in the region of the special struts. Erbel teaches that the non-porous section "will cause thrombosis or clotting of bodily fluid" (Para 83) as in treating an aneurysm. Erbel further teaches that the partial non-porous or graft covering is beneficial in that it blocks the tear or lesion or aneurysm, while at the

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same time allows blood to flow from the proximal to the distal end of the vasculature during implantation of the device. (Paras. 70-72).

9. It would have been obvious to one of ordinary skill in the art to incorporate a cover disposed about the stent in the area of radiopaque markers. Using a cover on the stent enhances the properties of the stent to cause thrombosis at the site of the aneurysm or tear while at the same time allowing blood to flow through the stent and the vasculature. Using radiopaque markers at the edge of the cover facilitates correct placement of the cover at the site of the aneurysm or tear in the body lumen. Erbel provides the motivation. The inventions are analogous with each other and with the instant invention therefore a combination is proper.

10. As to Claims 13 and 14, they are rejected to as Product by Process claims. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). (See MPEP § 2113) As stated above, the product is clearly anticipated by Cox in view of Erbel and so claims 13 and 14 are unpatentable even though the prior art was made by a different process.

11. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of Erbel as applied to claim 1 above, and further in view of Barone (USPN 6,613,078).

12. Cox in view of Erbel teaches a stent with a cover marked at the periphery by special radiopaque struts as stated above.

13. Cox in view of Erbel does not teach a second cover.

14. Barone teaches a stent with two covers shown in Fig. 7. The figure shows two stent grafts occluding where the vessel is ruptured but keeping the flow of the blood through the ostium of the vessel branch. Barone states that the use of 2 covers is desirable to repair blood vessels with lesions wherein the wall of the vessel is not in condition to receive and firmly retain an implanted graft (Col 2, lines 20-25 and Col 1, lines 8-17).

15. At the time of the invention it would have been obvious to one of ordinary skill in the art to combine the second cover of Barone into the stent of Cox in view of Erbel. Barone provides the motivation in that a stent with two covers enhances the function of the stent since it can be used to repair branched vessels with multiple lesions. The inventions are analogous with each other and the instant invention and so the combination is proper.

16. Claims 16-18, 22-24, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky (USPN 6,730,116) in view of Erbel et al. (USPN 2004/0116998).

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17. Regarding claims 16, 17, 23, and 24, Wolinsky teaches a stent having a longitudinal axis, comprising a plurality of serpentine bands having peaks and troughs and struts extending between and least one band includes special struts (Fig. 3, 28 and Fig. 8, 62a) with enlarged width with greater radiopacity. There is a plurality of struts on either side of the special strut having a complementary shape to the special strut. The special struts are in a region between the ends (edges) of the stent. One of the special struts is located in a serpentine band at one end and the other special strut is located in a serpentine band at another end of the stent. Wolinsky further teaches, "stents can be used to repair aneurysms" (Col. 1, line 36).

18. Wolinsky fails to teach a stent with a cover.

19. Erbel discloses an endovascular prosthesis (Fig. 3) or stent comprising an annular portion with a porous section (20) and a nonporous section (25). As to claims 34-35, the nonporous section (25) or cover is disposed about the circumference of the stent and does not cover the entirety of the stent as seen in Fig. 3. Erbel teaches that the non-porous section "will cause thrombosis or clotting of bodily fluid" (Para 83) as in treating an aneurysm. Erbel further teaches that the partial non-porous or graft covering is beneficial in that it blocks the tear or lesion or aneurysm, while at the same time allows blood to flow from the proximal to the distal end of the vasculature during implantation of the device. (Para70-72). The cover disposed about the stent in a region including radiopaque markers (35). The radiopaque markers designate the proximal and distal ends of the region of the cover. Erbel teaches that the "use of such radiopaque markers facilitates correct placement" of the stent (Para 90).



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20. It would have been obvious to one of ordinary skill in the art to incorporate a cover onto the stent to enhance the capabilities of the stent. Erbel provides the motivation that using a cover on the stent enhances the properties of the stent as it could then be used to promote thrombosis at the regions of aneurysms and tears while allowing blood flow through the lumen. He further provides the motivation for using radiopaque markers at the end regions of the cover. The inventions are analogous with each other and with the instant invention therefore a combination is proper.

21. As to claims 26 –28, Wolinsky in view of Erbel discloses a stent with a plurality of serpentine bands including a proximal band, a distal band and intermediate bands. The special struts are designated as the struts that are defining the periphery of the cover. In this case, the radiopaque struts outlining the cover are “special” over any other radiopaque strut or non-radiopaque strut because they serve the “special” purpose of defining the cover.

22. As to Claim 22, Wolinsky in view of Erbel teaches that using radiopaque markers to designate the proximal and distal ends of the region of the cover facilitates correct placement of the stent. However, Wolinsky in view of Erbel does not disclose the size of the cover and therefore does not disclose that the special struts are located anywhere between the middle of the stent and a position one half of the way from the middle of the stent to an end of the stent.

23. It would have been obvious to one having ordinary skill in the art at the time of the invention to alter the size of the cover depending on size of the vessel, the size of the stent and the size of the lesion that it is treating. And therefore the markers could be located at a position one half of the way from the middle of the stent to an end of the stent.

24. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky in view Erbel as applied to claim 16 above and further in view of Thornton et. al (USPN 6,551,350).

25. Wolinsky in view of Erbel meets the claim limitations as stated above but fails to disclose a stent in bifurcated form.

26. Thornton teaches a stent in bifurcated form as shown in Fig. 15. Thornton further teaches that a bifurcated stent is necessary when a defect, such as an aneurysm, is located very close to the bifurcation of a trunk lumen into branch lumens. Without a bifurcated stent, treatment becomes difficult because neither the trunk lumen nor the branch lumens provides a sufficient portion of healthy lumen wall on both sides of a defect to which a straight single lumen stent can be secured (Col. 1, paragraphs 6-8).

27. It would have been obvious to one skilled in the ordinary art at the time of the invention to design a radiopaque stent in bifurcated form. Thornton provides the motivation for the combination in that it is necessary to treat aneurysms and defects located close to the bifurcation of a trunk lumen into branch lumens. The inventions are analogous with each other and the instant invention, and so the combination is proper

***Response to Arguments***

1. Applicant's arguments with respect to claims 1, 2, 4-10, 13-15 and 34-35 have been considered but are moot in view of the new ground(s) of rejection.
2. Applicant's arguments claims 16-18, 22-28 and 34-35, filed 11/09/05 have been fully considered but they are not persuasive.
3. Regarding claim 16, Applicant states that Wolinsky does not disclose a "plurality of struts of the serpentine band adjacent one side of the special strut having *complementary* shapes thereto." Applicant argues the bend in the second adjacent strut is an "inflection point" found in identical struts far removed from the special strut. Examiner is not concerned with the struts that are far removed from the special strut. Nor is examiner concerned with the *reason* that the strut is shaped the way it is. Examiner is only concerned with whether or not the structure claimed invention is anticipated by or obvious over the prior art. Furthermore, as seen in Figure 8, the two adjacent struts on each side of the radiopaque marker clearly have a different "shape" than the rest of the struts. Applicant further states that the adjacent struts do not have a complementary shape because they do not *match* one another. Examiner was unable to find a definition of the term "complement" or "complementary" that states that the shapes *match*. Most of the definitions are derivatives of the following definition:

*"Something that completes, makes up a whole, or brings to perfection",*

as found in The American Heritage® Dictionary of the English Language, Fourth Edition Copyright © 2000. As an example, an angle related to another so that the sum of their measures is  $90^\circ$  are complementary angles. This does not imply that both angles are equal. Other examples include “complementary color” or “a wine as a complement to dinner”. Therefore Examiner maintains that the “shape” of the adjacent struts is *complementary*.

1. Regarding claim 26, Applicant states that the special struts defined by the examiner do not address the actual language of the claim. Applicant asserts that the special strut must have a radiopaque marker and not just be special because they define the cover. The claim recites “serpentine bands including special struts, each special strut having a radiopaque marker.” The special struts are not further defined to have any structure other than they have a radiopaque marker. As stated in the rejection, the radiopaque struts that define the cover are *special* because they serve the *special* function of defining the cover. This *special* function makes these radiopaque struts *special* over any other radiopaque struts. These *special* struts which are radiopaque and define the edges of the cover are only located in the intermediate bands as shown in Erbel. Applicant further asserts that Wolinsky does not show markers in the intermediate bands and that because of the structure of the stent there would be no expectation to include the markers in any other part of the stent. Wolinsky does not teach away from putting markers in other areas of the stent. Referring to Figure 8 of Wolinsky it is clear that the many connectors are not a factor in the placement of the marker. Furthermore, Erbel does supply the motivation for putting markers in the middle

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of the stent. As stated above: *Erbel teaches that the partial non-porous or graft covering is beneficial in that it blocks the tear or lesion or aneurysm, while at the same time allows blood to flow from the proximal to the distal end of the vasculature during implantation of the device. (Para70-72). The radiopaque markers designate the proximal and distal ends of the region of the cover. Erbel teaches that the "use of such radiopaque markers facilitates correct placement" of the stent (Para 90).*

### **Conclusion**

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-Th 8:30-6:00 Alternate Fridays 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

eh 

  
**ANH TUAN T. NGUYEN**  
**SUPERVISORY PATENT EXAMINER**  
